

**Notice of Allowability**

Application No.

08/892,695

Examiner

Karen A Canella

Applicant(s)

GRAY ET AL.

Art Unit

1642

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to \_\_\_\_.
2. ☒ The allowed claim(s) is/are 26-28 and 48-51, renumbered as 1-7, respectively.
3. ☐ The drawings filed on \_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date Nov 17, 2003
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

*Karen A. Canella*  
**KARENA CANELLA PH.D**  
**PRIMARY EXAMINER**

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tom Hunter on April 8, 2004.

The application has been amended as follows:

Claim 26 has been replaced with the following:

Claim 26. A method for screening for neoplastic cells in a sample, the method comprising:

contacting a nucleic acid sample from a human patient with a probe consisting essentially of SEQ ID NO:9, wherein the probe is contacted with the sample to form a stable hybridization complex;

detecting the formation of said hybridization complex, wherein an increase in the level of the hybridization complex relative to the level of a hybridization complex formed from a nucleic acid sample from non-neoplastic human cells is indicative of amplification of the sequence to which SEQ NO:9 has hybridized, and that said cells from a human patient are neoplastic cells.

Claim 48 has been replaced with the following:

Claim 48. A method of screening for neoplastic cells in a sample, the method comprising:

contacting a nucleic acid sample from a human patient with a probe that hybridizes selectively to a target polynucleotide sequence consisting essentially of the sequence of SEQ ID NO:10, wherein the probe is contacted with the sample to form a stable hybridization complex;

detecting the formation of a hybridization complex wherein an increase in the level of the hybridization complex relative to the level of a hybridization complex formed from a nucleic acid sample from non-neoplastic human cells is indicative of amplification of the target sequence, and that said cells from a human patient are neoplastic cells.

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Claim 49 has been replaced with the following:

The method of claim 48, wherein the nucleic acid sample is from a patient with breast cancer.

Claim 50 has been replaced with the following:

The method of claim 48, wherein the nucleic acid sample is a metaphase spread or an interphase nucleus.

Claim 51 has been replaced with the following:

The method of claim 48, wherein the probe consists of a polynucleotide sequence as set forth in SEQ ID NO:10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

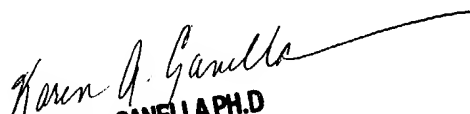
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

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04/08/04

  
**KAREN A. CANELLA PH.D.**  
**PRIMARY EXAMINER**